K001978 AUG 8 2000

II. 510(k) SUMMARY

Submitted By:
Thai Nippon Rubber Industry, Ltd.
49-49/1, EPZ-1
Laemchabang Industrial Estate
Thungsukhla, Sriracha, Chonburi
Thailand
Telephone: 66-38-490258-9
Fax: 66-38-490414

Contact Person:
Eli J. Carter
Consultant to Thai Nippon
1219 Little Creek Road
Durham, NC 27713

Date Prepared: June 28, 2000

Proprietary Name: 'One Touch'

Common Name: Male Latex Condom with Nonoxynol-9

Classification Name: Latex Condom with Spermicidal Lubricant (21 CFR 884.5310)

Predicate Device: Latex Condom with Spermicidal Lubricant (Suretex 'Royale' Condom) 510(k)# K981621

Description of Device: This condom is made of a natural latex sheath, which completely covers the erect penis with a closely fitted membrane. This condom is straight-walled with a reservoir tip; nominal length 180-mm, nominal width 52-mm, and nominal thickness 0.06mm. The condom is offered in natural latex color, red, blue, green, and yellow. It is lubricated with nonoxynol-9 lubricant.

This condom is designed to conform to established national and international voluntary standards including ASTM D3492, ISO 4074, and EN 600.

Intended Use of the Device:
This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted diseases, including HIV.

Technological Characteristics:
This condom has the same technological characteristics as the predicate condom identified above. The design is in conformance with ASTM Latex Condom Standard D3492 and that the condom is made of natural rubber latex.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 2000

Thai Nippon Rubber Industry Co., Ltd.
c/o Eli J. Carter
1219 Little Creek Rd.
Durham, NC 27713

Re: K001978
'One Touch' Latex Condom with
Nonoxynol-9
Dated: June 28, 2000
Received: June 29, 2000
Regulatory Class: II
21CFR 884.5310/Procode: 85 LTZ

Dear Mr. Carter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

VII. INDICATIONS FOR USE STATEMENT

510(k) Number	~~Not Known~~ K001978
Device Name	Male Natural Rubber Latex Condom with Spermicidal Lubricant
Indications for Use:	The Thai Nippon condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED
Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Krogmann

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001978

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)